GUIDELINES ON

ENVIRONMENTAL CRITERIA FOR THE REGISTRATION OF PESTICIDES

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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FOR THE REGISTRATION OF PESTICIDES

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Rome - March 1985

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PART I

ENVIRONMENTAL CRITERIA FOR REGISTRATION OF PESTICIDES

1. PRE-REGISTRATION HAZARD EVALUATION AND PREDICTION

1.1 Introduction

The risks to the environment from a pesticide or its formulated product depend on many factors such as its toxic properties, the amount applied, the formulation, method and time of application and particularly the intensity of use, mobility and persistence in the environment. In practice, information of environmental significance comes from three basic sources; application and use pattern, the fate and possible occurrence of residues in relevant parts of the environment and the effects of predicted exposures on non-target species (see Figure 1, page 12).

Some pesticide effects on wildlife may be too complex, subtle, or delayed to be detected by ordinary routine testing in the laboratory or the field, and, in any case, it is obviously impossible to cover in such trials all the variety of conditions under which the pesticide may be used in practice. Nevertheless, experience has shown that in many instances, prediction can be made of probable environmental effects of the use of a compound from a consideration of certain basic studies.

Data have to be developed prior to registration to allow a reasonable judgement to be made of the environmental behaviour of the product when applied according to the recommendations for use. Such data are essentially predictive and are intended to describe those characteristics of the product relevant to the environment. They should be sufficiently comprehensive to enable the authority to make a reasonable judgement of environmental behaviour of the product for the uses proposed, but they do not seek to give data on the actual behaviour of the product in all the many environments in which it will be applied. However, the actual test programme has to be designed according to the characteristics and conditions of use of the product and the test species carefully selected in order to justify broad environmental predictions being made on the basis of results from a feasible test programme.

1.2 Primary Data Needed for Predicting Environmental Effects

1.2.1 Properties of the Pesticide

The recommendations of the 1977 Ad Hoc Government Consultation listed a number of data requirements, including physical-chemical properties, toxicology and residues recommended as being necessary for registration purposes. The following data are necessary to identify and describe the active ingredient and the product.

Identity of Active Ingredient

- common name proposed or accepted by ISO
- structural formula
- chemical name (IUPAC nomenclature)

Physical-Chemical Properties of Active Ingredient

- melting/boiling point
- density
- physical state
- absorption spectra - ultra-violet, visible and infra-red

Composition of Technical Grade Material

- the nature and amount of isomers, impurities and other by-products, together with information on their possible variation expressed as w/w.

Properties of Formulated Product

- type of formulation, (e.g. water dispersible powder, emulsifiable concentrate, powder, granule, seed-dressing, aerosol)
- content of active ingredient(s)
- content and precise nature of components included in the formulation of the product, e.g. technical grade, chemical adjuvants and inert adjuvants
- storage stability (in respect to composition and physical properties related to use)
- physical characteristics e.g. density, particle size distribution
- acidity/alkalinity

Some of these above descriptive characteristics are obviously important in predicting environmental behaviour, in particular, type and content of formulation and concentration of active ingredient.

The following properties, which influence mobility and degradation are of paramount importance in the evaluation of the environmental fate of a pesticide:

- vapour pressure (figures should be given at a stated temperature preferably in the range of 20-25°, but only when above 10^{-5} millibar).
- solubility in water (at a stated temperature preferably in the range of 20-25° C)
- partition coefficient between water and an appropriate non-miscible solvent (e.g., n-octanol)
- chemical stability
- adsorption/desorption characteristics

Assessment of fate of a pesticide after its release into the environment is essential to the assessment of environmental loading and subsdequent evaluation of exposure and risks offered by that chemical (see Figure 1). Fate, in this sense, is defined as the process of transport, transformation and final disposition of a chemical by natural means after it is released to the environment.

Fate and Mobility Studies are therefore the most important sources of information on the fate of a pesticide in the environment. These studies usually include:

- Analytical procedures for estimating residue levels
- Degradation rates and residue levels in plants, soil and water
- Identity of major metabolites in plants, soil and water
- and leaching through soil.

Toxicity

The data on the toxicity of a pesticide used for assessing possible hazards to man normally include information on the following:

- acute toxicity
- semi-chronic toxicity
- chronic toxicity
- special studies, such as metabolism studies, teratogenicity, reproduction and other appropriate studies.

Although most of these studies are carried out with rodents, some of the results are also relevant for the prediction of potential effects on non-target species in the environment (e.g., bioaccumulation).

However, since many naturally occurring organisms belong to other taxonomic groups the following toxicity data on other species form an important additional part of the primary data needed for predicting potential adverse effects to non-target species:

- acute oral toxicity to one bird species. Suitable species include: pigeon, quail, pheasant, duck and the Bengalese finch. The hen is not a suitable species for this purpose.
- acute LC50, 96-hour exposure, on one suitable fish species, e.g., the rainbow trout or zebra fish.
- acute LC50, 48-hour exposure, on one suitable fish-food species, for example Daphnia.
- acute oral LD50 and contact toxicity on honey bees.

Appropriate test procedures for developing these data are given in Part II of this report.

The main reason for developing agreed test procedures is to ensure that the data are reliable and adequate. This normally means that the procedures used must be reviewed and validated but since it is not possible to validate all test procedures, the most practical approach is to establish a basic set of validated and accepted test procedures which can be applied with modifications as necessary for each particular chemical.

Registration authorities must also be able to judge the validity of data. If the data are derived from procedures that have been validated, there are relatively few problems. However, some flexibility in procedures is necessary for practical reasons. If major changes are made in testing procedures, it may be necessary to submit data on the validation to satisfy the authority.

A further factor contributing to validity of data is the ability of the scientists concerned. These must be suitably qualified and experience and have appropriately equipped laboratories for their work. It is worth noting that studies carried out in a particular laboratory should not be beyond the capacity of the laboratory, its equipment and the experience of its personnel. Where new procedures are introduced, the personnel concerned should be properly trained beforehand.

1.2.2 Application - Influence of use patterns

The way in which a pesticide is used can greatly influence its potential environmental effects. Very toxic or persistent compounds may not cause environmental damage if used in ways which do not expose non-target organisms to harm. Conversely, compounds of low toxicity or low persistence can cause damage if applied at high or frequent doses. A number of characteristics of the use profile can influence potential environmental effects and these should all be taken into account.

Patterns of use of pesticides are not static but typically undergo expansions to new crops or uses, especially in the first few years after introduction. Thus a continuing review of use patterns for their environmental significance is required in the registration process.

Formulations are usually designed to optimize performance and minimize operator risks. They often influence the persistence and bioavailability of a pesticide and may thus modify potential environmental effects. For example, encapsulation can extend the persistence of a compound but may localize its biological effects.

Methods of application are closely associated with the type of formulation and range through general to localized soil treatment, ultra-low to high volume sprays from ground to air.

Site of application can influence the environmental effects. Although the effects of a pesticide are normally intended to be restricted to the site of application, since most pesticides have some mobility, environmental effects can occur some distance away. A particular use in one environmental system may or may not influence other systems, for example, a forest canopy may screen out most of an aerial spray whilst applications into soil may eventually lead to leaching into water. More localized treatments tend to cause less environmental problems than generalized treatments.

Time of application is also important. For the control of some pests, pesticide applications may be necessary at a time when beneficial species can be at risk, but this can often be avoided. For example, harm to bees can be reduced or even avoided by not spraying when bees are actively foraging.

Rate of application clearly influences environmental effects. However, the relationship between dose and effect is not linear. For example, for the environmental effect to be doubled an increase in dosage of a pesticide of up to an order of magnitude may be needed. Nevertheless, even small doses of very toxic chemicals can cause environmental effects.

Scale of use influences the effect of a pesticide on the environment. Small localized uses, even of a very toxic chemical seldom cause wide or long-lasting damage. On the other hand, widespread use of a less toxic pesticide may have quite large effects. Frequent and widespread use can result in the development of resistance, not only in pests but also in non-target organisms.

Climatic and geographical locality can be of prime importance in influencing the extent of environmental effects and it is not valid to extrapolate data uncritically between temperate and tropical areas. A pesticide which may be very persistent in a temperate country may be much less so under moist and hot tropical conditions. More intense solar radiation may

result in photodecomposition or conversion of the parent compound. In some cases, more toxic compounds may be formed. The toxicity of some pesticides to aquatic organisms varies with the temperature and the assessment of toxicity studies should consider possible differences between temperate and tropical environments.

The above information on application and use patterns is vital to the estimate of the expected environment concentration and the identification of probable sites of deposition. These enable an estimate to be made of the initial level of exposure for the organisms that inhabit the various parts of the environment. It is important to estimate which elements of the environment (vegetation, soil, air or water) receive the main burden of the pesticide. This information is vital to the prediction of possible environmental effect.

By careful selection of the formulation and methods of application it may be possible to minimize the movement of a product away from the treatment area. Formulation can affect the bioavailability of the pesticide. For example, granular formulations incorported into the soil minimize exposure to aerial species, whereas formulations such as a seed-dressing or bait may present a direct hazard to birds and small mammals. The aquatic environment is particularly susceptible to adverse effects and direct application to water (e.g., pest control in rice paddies; aquatic weed control) requires specially careful consideration.

Drift is a further factor to be considered. Aerial application has a greater drift potential than ground based application. While drift may sometimes be used deliberately to treat target pests, the potential effects to nearby areas paricularly water, must always be considered.

1.3 Prediction of environmental fate and effects from primary data

The role of the registration process is to assemble sufficient basic data for a reasonable prediction of environmental effects to be made. Where such effects are envisaged additional information may be needed before the chemical can be approved and its commercial use accepted.

1.3.1 Principles of prediction

The data available to the authority prior to registration may be used to estimate likely effects on the local environment when the product is used according to recommendations. From a knowledge of the habitat of the species concerned and the sites of deposition, as well as the mobility and degradation rate of a pesticide it is possible to estimate the exposure of the species to the pesticide.

The toxicity data available for the different organisms tested may then be used to estimate the effect of the likely exposure on related species at risk in the area. The predictive value of the basic data depends on the concept of extrapolation from one species to another. Experience has shown this to be a valid concept although it is clearly more reliable with closely related species.

By applying these consideration it should become apparent whether particular groups of wildlife are likely to be at risk when the product is used as recommended. Some organisms tend to be at greater risk than others, for instance when water is contaminated, aquatic organisms and particularly fish may be continuously exposed to the chemical. Similarly, predatory species and parasitoids tend to be more vulnerable than their prey to some pesticides. Organisms with food sources likely to be contaminated such as seed or plant consumers may be particularly at risk. It may be possible to recommend specific precautions to be taken or to develop modifications in the proposed uses to minimize the risk of these effects occurring in practice. A product with high avian toxicity could lead to difficulties if it were likely

to contaminate food for the species in question. Similary, compounds of high toxicity to fish would have to be used in a way which prevented excessive exposure to valuable aquatic organisms at risk in the area.

1.3.2 Prediction of fate in the environment

Environmental hazards can often be predicted successfully from physical-chemical data and data on mobility and fate derived from laboratory studies.

Volatility affects the distribution of a pesticide between soil or water and air. Vapour pressure, the main guide to the volatility of a compound, can be measured under standard conditions. Additional information can be obtained by measurement of volatilization from soil or water systems in the laboratory. Particle size, environmental factors such as temperature and moisture, and interactions with environmental substrates are also important and should be considered when predicting potential effects. For example, a volatile compound, which is highly absorbed or used in a dry climate, may not cause effects. Interpretation of volatile data is dependent upon the proposed use pattern, e.g., a volatile chemical incorporated into soil may persist much longer than when left on the soil surface. A high vapour pressure may add to, or detract from, environmental effects. More volatile compounds tend to persist less, thus presenting less environmental effect. Conversely, high volatility means escape into the atmosphere and possible transfer to other media. However, in general, a compound with a high vapour pressure is usually less liable to cause environmental contamination than one of lower vapour pressure. Pesticides are most likely to be dissipated by volatilization in tropical areas than in temperate areas.

Water solubility influences the mobility of a pesticide through ecological systems. Pesticides of high water solubility will have a greater tendency to reach water systems than those which are less soluble or adsorbed and not readily leached. Such pesticides may be a particular problem for aquatic systems.

Octanol-water partition coefficient can be important in appraising the likelihood of uptake and distribution of a pesticide into a biota. A high coefficient may already be indicated from solubility studies and is presumptive evidence of the likelihood of a pesticide accumulating in living organisms.

Adsorption of a pesticide on to soil surfaces varies greatly. Strong adsorption reduces biological availability, leaching and movement into water but may increase resistance to degradation. Adsorption is influenced by the chemical properties of the pesticide molecule and soil properties such as the type and amount of clay and organic matter, soil surface area, soil structure and pH, temperature, moisture content and salt concentration. Organic matter is probably the single most important factor. The degree of potential soil adsorption can be predicted by laboratory tests and the use of the empirical Freundlich equation.

Desorption implicitly influences the leaching of a pesticide through soil. Such desorption can be predicted from laboratory leaching tests through soil columns or thin layer chromatography.

Degradation data are important in predicting environmental exposure. Rapid degradation of the pesticide and its metabolites would indicate that problems resulting from persistence are unlikely to occur. Three methods of degradation, photochemical, chemical and biological, need to be considered but when considering possibilities of accumulation, frequency of application and environmental factors, especially temperature, should be taken into account. Knowledge of the identities of the major metabolites is desirable: they may be more or less toxic than the parent compound.

Persistence can be defined as the ability of a chemical to retain its molecular integrity, and hence its physical, chemical and functional characteristics in the environment through which it is transported and distributed following its environmental release. The inverse of chemical persistence is chemical degradability or transformation, which can be brought about through physical, biological, chemical and photochemical mechanisms.

The susceptibility or resistance of a chemical to degradation will determine, to a large extent, its residence time in a particular medium, environmental compartment, or ecosystem. Persistence is a major factor in determining the steady-state concentration that a chemical may attain in a particular medium or in a compartment thereof, i.e. its residence time. Thus, if the rate of degradation in a medium or environmental compartment exceeds its rate of entry, there is less likelihood of its achieving significant environmental concentration levels in that medium or compartment. However, there could still be cause for concern if the rate of uptake by biota in those areas exceeded the rate of chemical degradation, or if dispersion or transport were poor so that the pesticide tended to concentrate in small areas resulting in relatively high concentration of the pesticide.

1.3.3 Prediction of environmental effects

Use of mammalian toxicity data

The mammalian toxicity data will usually indicate the general toxicological properties of the pesticide and the tests often identify mode of action and specifically vulnerable organs or function.

The acute oral and dermal toxicity to rats and mice allows a direct assessment of acute hazard to wild rodents and other mammals and is of value in other assessments. Comparison of acute and semi-chronic data for laboratory mammals allows a first assessment of the possibility of long-term (chronic) effects in wild species. A knowledge of metabolism of pesticides in mammals may also give some preliminary indication of metabolism and possible accumulation in other species.

Use of toxicity data from other species

Since many naturally occurring organisms belong to other taxonomic groups toxicity data on other species form an additional part of the primary data needed for predicting potential adverse effects to non-target species.

Effects on birds

The oral toxicity (LD50 and/or LC50) or the outcome of range finding studies of a pesticide to birds when taken in conjunction with the levels that could occur in the food of important bird species should suggest whether or not the latter may be at risk and hence if further tests under more practical conditions should be undertaken. In extrapolating between bird species, their age, size and food intake should be considered.

Effects on fish

The 96 hour acute LC50 for fish, when taken in conjunction with the expected exposure levels, indicates whether fish may be at risk. Factors of particular relevance are age, size and behavioural/physiological characteristics of the fish and whether they live in still or running water.

Effects on fish food species

The toxicity of a pesticide to fish food species can be represented by its toxicity to Daphnia spp, known to be particularly sensitive indicator. Again the potential effects can be assessed by comparing the toxicity data with the exposure levels expected in the environment. It should be borne in mind that effects on fish food are particularly dependant on the

persistence of the pesticide because populations of the relevant species often recover quickly. If persistence is short and exposure levels are low compared to the laboratory LC50 value, it is unlikely that the intended use will give rise to practical problems.

Effects on honey bees

If the laboratory data indicate low toxicity, the pesticide can be considered safe to bees. However, the effects of a compound with a high laboratory toxicity to bees can often be overcome in field use by careful selection of formulation, methods of use and timing of application.

1.4 Additional data needed for predicting environmental effects

1.4.1 Introduction

Assessment of the primary data developed in Section 1.2 may well identify situations which require further study. Indeed, the need for further studies at this stage in the process of registration should normally depend on whether possible harmful environmental effects can be predicted and identified. The procedures to be followed in any further testing should be designed to assess the probability of occurrence of any harmful effect occurring if the pesticide product were to be used on a practical scale for the registered uses. The need for any specific kind of tests to be undertaken will often be clarified by consideration of experience with the use of other pesticides under comparable condition.

A proposal for the sequence of hazard evaluation, including the consideration of additional data is shown schematically in Figure 2, page 13.

This section deals with the criteria on which requests should be made for additional studies. These may include field experiments to complement the predictions made from the preliminary laboratory findings.

1.4.2 Fate in the environment

In many cases a knowledge of the use pattern, particularly the site and mode of application (e.g., to vegetation, soil or water), together with information from the primary data, enables a good estimate to be made of the likely distribution and levels of residues in the various sectors of the environment. Nevertheless, circumstances can arise where further studies are necessary to amplify the primary information. Examples of relevant situations which justify additional testing requirements are:

Leaching through soil

If a compound proves to be leached readily and there are fears that it may contaminate water bodies, further leaching tests under field conditions may be required to quantify the risk involved.

Degradation product in soil

If degradation products which might be harmful to the environment occur in soil, data on their behaviour in the environment may be needed.

Possibilities of accumulation with stable lipophilic compounds

If the pesticide or a major metabolite is strongly lipophilic, degrades slowly in the biota and it is consdered that there is a possibility of accumulation, residue studies in species considered to be at risk and at various trophic levels should be required.

Appropriate test procedures for these requirements are dealt with in Part II of this report.

1.4.3 Environmental effects

The following considerations form the basis on which additional data are required for a fuller assessment of environmental effects.

Aquatic species

If the pesticide is likely to persist in an aquatic environmnet in appreciable quantities and for an appreciable time (due either to slow degradation or frequent application), specific additional toxicity tests should be considered. These may include:

(a) prolonged exposure of suitable test organisms (fish, Daphnia, etc.) for periods of up to 30 days;

(b) reproduction tests with Daphnia and fish;

(c) other tests which may be indicated from the basic toxicological properties of the compounds, e.g., behavioural effects;

(d) field studies (including field enclosure studies) if the results (a), (b) and (c) and of the primary laboratory studies give rise to serious doubts or when the product is applied intentionally to the water body. The special value of these studies is that they allow observation of the recovery of affected populations which can be carried out realistically only under field conditions. Moreover the suspended matter and other factors characteristic of natural waters can have a profound effect on the results obtained but cannot be reproduced readily in the laboratory. In addition, such studies have the advantage that the effects of interrelationships between the various species in the system are also reflected in the results. Techniques for conducting studies of this kind are still under active development but they should be conducted in water bodies where the population dynamics are well understood.

Birds

If a pesticide is applied in such a way as to give rise to the possibility of a significant exposure to birds and it has been shown already to be of high acute avian toxicity further special studies on bird species may be required. Potentially high exposures can occur with seed dressings or in cases where bird food may be contaminated.

Examples of relevant tests on birds are:

(a) short-term oral feeding studies with additional species;

(b) long-term feeding studies with a suitable indicator species: the length of the exposure period in the study will depend on the type species chosen and the problem involved;

(c) a reproduction study, if the data from (a) and (b) indicate the need.

Soil Organisms

If a pesticide is likely to persist in the soil in appreciable quantities and for an appreciable time (due either to slow degradation or frequent application), it may affect a number of soil organisms and their functions, which may be important in the maintenance of soil fertility.

With microorganisms studies usually start with an estimate of the effect of a pesticide on their overall function as indicated by their respiration rate under laboratory conditions. If this is significantly changed, its importance under field conditions can be further studied using a leaf-litter bag test.

Among macroorganisms earthworms are often regarded as particularly important both from an agricultural and environmental point of view. Laboratory or field data on the toxicity to earthworms are therefore relevant. Where the pesticide is known to be of high avian toxicity residue data from earthworms sampled from treated plots should also be obtained. Information on the contribution of earthworms and other soil macroorganisms to the decomposition of organic debris can be obtained by suitable design of the above-mentioned leaf-litter bag test.

Appropriate test procedures for the above requirements are dealt with in Part II of this report.

2. APPRAISAL OF ENVIRONMENTAL EFFECTS AND REVIEW OF USES

On the basis of the data developed from both the primary and further studies it should now be possible to appraise the environmental characteristics of the product. With this appraisal it is possible to review the proposed uses and to decide if modifications are needed to avoid unacceptable environmental effects. It may be possible, for example, to minimize the exposure of vulnerable elements of the environment by altering the timing of application, the formulation, phasing of the dosage (i.e. split applications) or application techniques. As examples: (i) Hazard to bees can be eliminated largely by not spraying when bees are foraging; (ii) undue interference of a pesticide with predators and/or parasites can often be reduced by adjusting the use pattern; (iii) drift contamination of vulnerable aquatic habitats may exclude aerial application in the vicinity of the water body concerned, (iv) a slow release formulation can sometimes reduce damage in aquatic systems by avoiding large initial concentrations.

Where such opportunities can be identified, discussion between the regulatory authority and the notifying company, with outside consultation where necessary, is probably the most productive way of achieving a balance between the environmental and other aspects of the use.

However, in this subject there can be issues that still remain difficult to decide particularly where longer term effects could arise. It is difficult to reach a point of certainty on environmental issues and the concept of balancing risk and benefit must apply in all registration decisions. Many authorities, when faced with uncertainties have been able to resolve them by observing the effects of the product in the early years of use after registration and, where necessary, have introduced appropriate amendments to the use pattern. This issue is dealt with more fully in the following chapter.

3. POST REGISTRATION ACTIVITIES

3.1 Introduction

After a pesticide has been registered for certain uses it is desirable for the competent authority to be able to confirm that the predictions made on environmental effects at the time of registration are valid. If doubts arise about the validity of the predictions, field surveillance and monitoring studies may have to be carried out both on the occurrence of residues and on possible biological effects. If the surveys indicate unsuspected or harmful effects, additional laboratory or other work may be necessary for reconsideration of the registered uses; on the other hand

absence of effects is reassuring and can be valuable in considering extension of registered uses. The reports of previous expert consultations of FAO, particularly those held in September 1975 and in September 1977, and the OECD Report of the Wildlife Sampling and Analysis Programme contain examples and guidance concerning the planning and conduct of such studies. Whenever there is a substantial change in the proposed use pattern, for example, additional crops or different methods of application, or a marked increase in the quantity used, then the implications of these changes should be considered in the light of available data. Additional work may be required to extend the initial predictions to the new use pattern.

3.2 Chemical Monitoring and Surveillance

Surveillance of residue levels should be made in the various compartments of the environment that may be affected. The sampling and analysis of several species and abiotic components may have to be done to provide information on the environmental distribution pattern of the chemical in the species or components which can be used as indicators in the monitoring programme. If the results of such a survey show that residues are widespread at biologically significant levels a monitoring programme may be needed.

The aim of any monitoring programme should be well and clearly defined before decisions are taken on the details of the sampling required and the initial planning should involve statisticians as well as biologists and chemists when appropriate. The characteristics of the chemical and derived products such as metabolites will indicate the kind of monitoring studies that may be needed. For chemical residue monitoring, the timing, kind, location and number of samples must be related to the use of the pesticide and the anticipated environmental distribution. Accordingly emphasis should be on the aquatic or other appropriate components of the environment. If organisms are to be selected as indicators because they are likely to accumulate the chemical, the species should be abundant and easy to obtain in adequate numbers.

3.3 Biological Monitoring and Surveillance

The biological effects of pesticides on the environment can be assessed by monitoring changes in populations of either the key indicator species that were selected for chemical monitoring or by choosing other species, either because of their known sensitivity to a pesticide, or because they are particularly vulnerable due to their position in the particular ecosystem. Biological monitoring can also be done by assessing changes in species diversity in ecosystems or by studying physiological and behavioural parameters. Terrestrial or aquatic ecosystems should be selected for study depending on the properties, use and method of application of a pesticide and the particular hazards being investigated.

To accomplish a meaningful biological monitoring programme, baseline data should be obtained on the ecology of the areas concerned. It may be essential that regional ecological investigations should be made prior to application of pesticides, especially where large areas are concerned. Special attention should be given to environmental effects which may indirectly affect the local human population in the areas where the pesticides are applied.

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FIGURE 1.

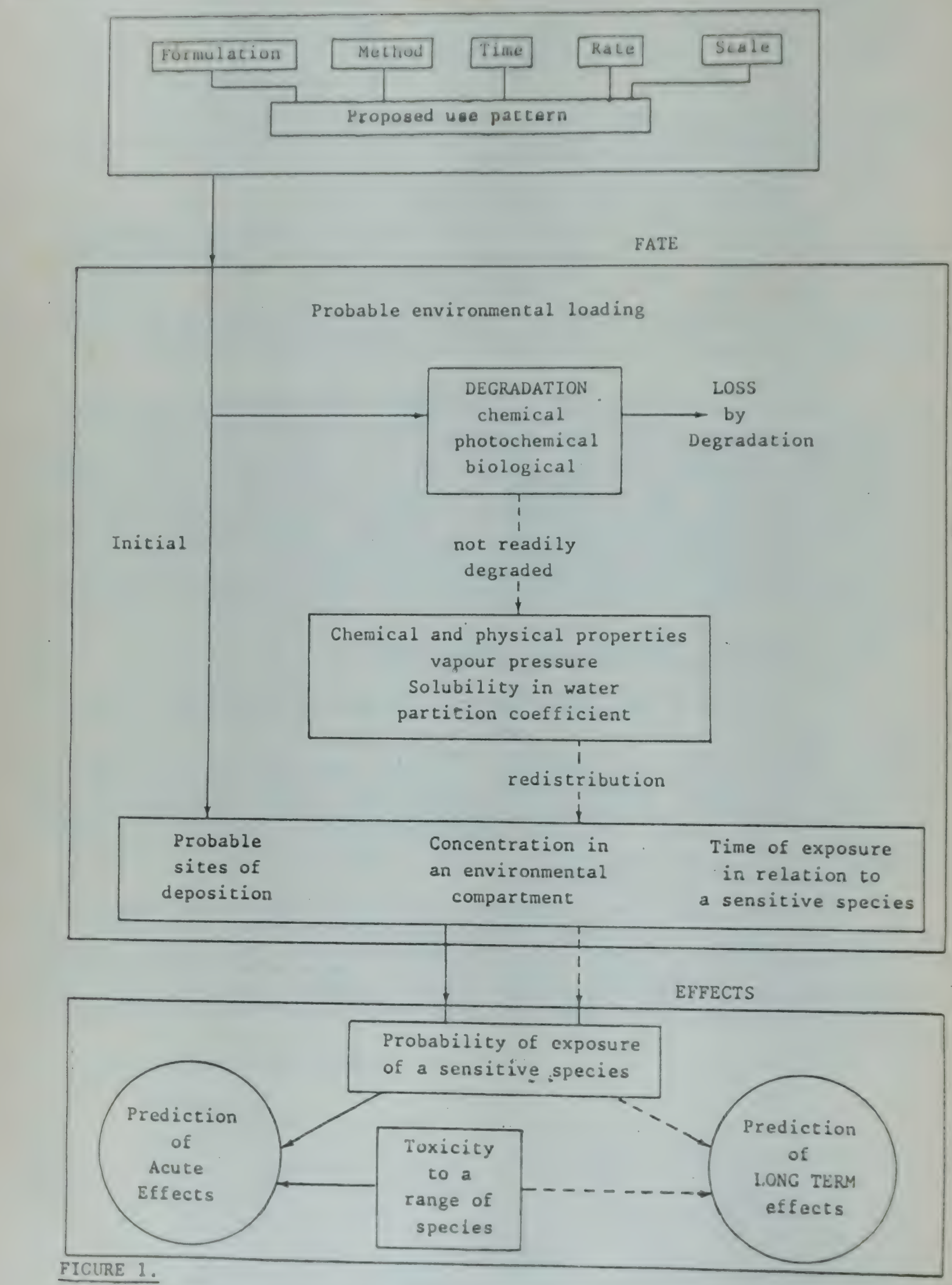

FIGURE 1.

FIGURE 2.
GENERATION AND ASSESSMENT OF DATA FOR THE EVALUATION OF ENVIRONMENTAL HAZARDS

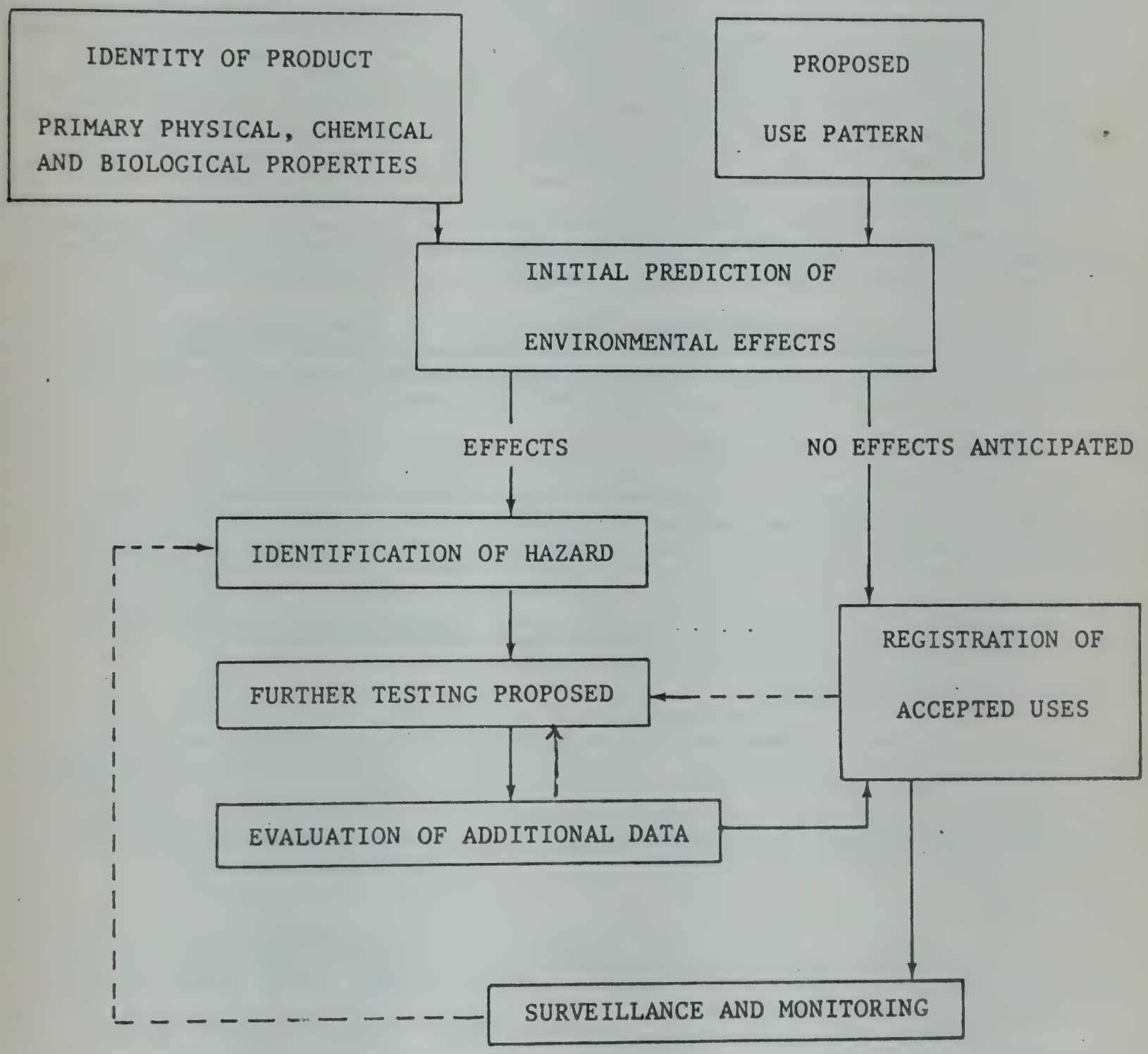

FIGURE 2

GENERATION AND ASSESSMENT OF DATA FOR THE EVALUATION OF ENVIRONMENTAL HAZARDS

PART II

GUIDELINES FOR APPROPRIATE TEST PROCEDURES

The concept of pre-registration hazard evaluation and prediction from primary and additional data has been described in Part I of this report. Part II lists test procedures considered to be appropriate in providing data for the assessment of the potential environmental effects presented by a pesticide.

The test procedures and sequences described originate from a variety of sources. Many are well established methods that have been used successfully for many years in research as well as in connection with pesticide registration. Many others have been devised specifically for regulatory purposes by individual governments and international organizations. For those topics for which testing has only recently been required appropriate test procedures are still in a state of development.

The test procedures and sequences referred to in Part II fulfil common criteria, the most important being that they are widely applicable and can be performed adequately yielding reliable, accurate and reproducible results.

References to some guidelines, particularly from national agencies and international organizations refer to current guidelines. In view of the continuous procedures for updating guidelines, it should always be ascertained if the latest version varies from the reference quoted.

4. PHYSICAL-CHEMICAL PROPERTIES

The physical-chemical properties usually provided for regulatory purposes and listed in Part I are necessary to identify and describe the active ingredient and the product. Certain of these properties are important in predicting environmental behaviour. Vapour pressure, water solubility, and octanol/water partition coefficient have particular value in the prediction of the environmental behaviour of a pesticide and noted the following appropriate test procedures for the determination of these characteristics.

4.1 Vapour Pressure

The vapour pressure of a pesticide is important in assessing its distribution in the environment. It is the major property which can be used to calculate the volatility of a substance (5.1.1) and to predict whether a pesticide is likely to enter the atmosphere in significant concentration. Conversely an estimate can be made on the distribution between air and other compartments.

Definition

Vapour pressure is defined as the saturation pressure above a solid or liquid substance at a particular temperature. The S.I. unit for pressure is the Pascal (Newton/m2.).

Criteria and test sequence

Determination of vapour pressure should not be required for pesticides with standard boiling point of less than 30°C.

The vapour pressure at a given temperature is measured in the laboratory at that temperature or calculated from the experimental vapour pressure curve. The vapour pressure curve is the graphical or tabular presentation of the vapour pressure over a range of temperatures. If calculated from the vapour pressure, it must be ascertained that a change of state or a transition point or decomposition does not occur within the considered temperature range.

Test requirements

The use of analytically pure active ingredient is preferred; however technical material can also be used for the static and gas-saturation systems.

Appropriate test procedures

Several methods are reported in the literature (ref. 1 to 4) that cover a range of vapour pressures from less than 10^{-3} Pa to 10^{5} Pa, but no single method covers the entire range of vapour pressures. Five methods are recommended, each covering a definite range of vapour pressure (ref. 3).

1. Dynamic method (10^{3} Pa up to 10^{5} Pa, between 20° and 100°)
In the dynamic method, the boiling temperature which pertains to a specified pressure is measured.

2. Static method (10 Pa up to 10^{5} Pa, between 0°C and 100°)
In the static process, at thermodynamic equilibrium the vapour pressure established in a closed system is determined at a specified temperature. This method is suitable for one component and multicomponent solids and liquids.

3. Isoteniscope (from 10^{2} Pa to 10^{5} Pa, between 0° and 100°)
This standardized method is also a static method but is usually not suitable for multicomponent systems. Additional information is available from ref. 2.

4. Vapour pressure balance (10^{-3} Pa to 1 Pa, between 0°C and 100°C)
The quantity of substance leaving a cell per unit time through an opening of known size is determined under vacuum conditions such that return of substance into the cell is negligible (e.g. by measurement of the pulse generated on a sensitive balance by a vapour jet or by measuring the weight loss).

5. Gas saturation method (up to 1 Pa)
A stream of inert carrier gas is passed over the substance in such a way that it becomes saturated with its vapour and the vapour is then collected in a suitable trap. Measurement of the amount of material transported by a known amount of carrier gas is used to calculate the vapour pressure at a given temperature.

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4.2 Water Solubility

The water solubility of a chemical is an important parameter determining its environmental transport and distribution. In addition, water solubility can affect adsorption and desorption on soils and volatility from aquatic systems, as well as possible transformation by hydrolysis, photolysis, oxidation, reduction and biodegradation in water.

Definition

Water solubility of a pesticide is defined as its saturation concentration in pure water at a given temperature. Water solubility is generally expressed in g/l or mg/l, though the S.I. unit is kg m^{-3}.

Criteria and test sequence

Evaluation of water solubility should be carried out for every pesticide which is stable in water during the required test period. A preliminary test to establish the approximate value of solubility is useful for the choice of the final method of measurement.

Test requirements

The purity of the test substance should be specified. Very pure water (double distilled) has to be used. Deionized water should not be used unless redistilled.

Temperature control is needed and the limits within which the temperature is maintained should be given. Tests are frequently carried out at 20°C. If climatic conditions make it relevant and an environmental gradient is expected, tests should be carried out at two temperatures.

Care has to be taken to avoid errors arising from the aggregation of finely dispersed particles of hydrophobic compounds.

Appropriate test procedures

Several methods are reported in the literature (ref. 1, 2, 3, 4) but no single method covers the entire range of water solubility. At least two methods are therefore needed; the first is applicable to substances of low solubility (less than 10^{-2} g/l) and the second to substances of higher solubility (more than 10^{-2} g/l).

1. Test for solubilties lower than about 10^{-2} g/l (ref. 4).

The method is based on the elution of the pesticide with water from a microcolumn which is charged with an inert carrier material, such as glass beads, silica gel or sand, and an excess of test substance. The water solubility is determined when the mass concentration of the eluate is constant, tested at different flow rates. It must be ascertained that the identity of the pesticide is not changed during the procedure.

2. Test for solubilities higher than about 10^{-2} g/l (ref. 4).

The substance (pulverized if solid) is dissolved in water at a temperature slightly higher than the test temperature. When saturation is achieved, the mixture is cooled and kept at the test temperature under stirring as long as necessary to reach equilibrium. Undissolved particles are removed from the solution and the dissolved pesticide is determined by a suitable specific analytical method.

3. Test for solubilities of gaseous and volatile compounds.

No appropriate methodology can presently be proposed.

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4.3 Octanol/Water Partition Coefficient

The octanol/water partition coefficient (P) is used as an indicator of bioaccumulation potential in living organisms.

Accumulation and transport of a chemical substance in living organisms are governed by polarity, water solubility, affinity for fatty tissues, and the nature of potential binding to biological receptors. The octanol/water partition coefficient is a measure for the distribution of a substance between the lipophilic and water phases of the test system. It therefore serves as an indicator of bioaccumulation potential in fatty tissues. Accumulation potential is an important factor in hazard assessment. In conjunction with data on degradation, accumulation potential may be used to identify chemicals which may be transported via food chains.

Definition

The partition coefficient of a chemical between two largely immiscible solvents is defined as the equilibrium ration of the molar concentrations (c) of the substance dissolved in the two-phase system. For a dilute solution of a pesticide in the octanol/water system, it is:

$$P = \frac{c(\text{octanol})}{c(\text{water})} \qquad (1)$$

The partition coefficient, P, is a constant for a given pesticide at a given temperature, and it is usually expressed in the form of its logarithm to base ten (log P).

If the chemical does not dissociate or associate in water and octanol, then equation 1 applies, provided that the concentration in either phase is no more than 0.01 mol/l. Deviations from equation 1 are indicated by the fact that the partition coefficient becomes dependent upon the concentration of the solutions.

Criteria and test sequence

The determination of octanol/water partition coefficient should not be required for solid and liquid substances whose water solubility is less than about 10^{-6} g/l, or greater than 2 g/l.

Substances which dissociate or associate in water and/or octanol will not show a constant value for P with varying concentrations due to speciation effects.

Because of the multiple equilibria involved, the recommended method should not be applied to compounds which reversibly ionize or protonate and the use of buffer solutions in place of water should be considered for such compounds.

A preliminary estimate of the partition coefficient can be done by calculation (ref. 1, 2) or by use of the solubilities of the test substance in the pure water (Sw) and control (So). In this latter case the estimated value of P is given by the ration So/Sw.

Test requirements

A comparison betweeen calculated and experimentally determined P values (ref. 2) is recommended.

Very pure solvents and active ingredient should be used.

Appropriate test procedures

Several methods can be used to measure the partition coefficient in the laboratory.

A commonly used method (ref. 3, 4) is to introduce the pesticide into octanol and water, to mix the biphasic system thoroughly to assure equilibrium and measure the concentration of the chemical in each of the two phases. However, application of this technique becomes increasingly difficult at higher values of lipophilicity (log P more than 4).

Chromatographic methods based on as high pressure liquid chromatography (ref. 5) and reversed phase thin-layer chromatography (ref. 6, 7) are available from the technical literuature. Such methods show promise as acceptable alternatives but require further validation.

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5. MOBILITY AND FATE IN THE ENVIRONMENT

5.1 Mobility in the Environment

The mobility of a pesticide is its ability to move within the environment and it is therefore important to consider it as a determinant for the transport of the pesticide and its degradation products. A number of characteristics, mostly influenced by physical-chemical properties, are significant for the prediction of mobility thus permitting estimates to be made on the distribution between environmental compartments. Volatility, adsorption/desorption and leaching are the most important of these.

5.1.1 Volatility

Volatilization is a method of redistribution of pesticides between air, soil and water. When the vapour pressure, the water solubility and the soil adsorption/desorption characteristics are known, an estimate can be made whether volatilization is likely to occur under practical conditions.

Criteria and test sequence

Evaluation of volatilization should be made for all compounds likely to enter the soil or aquatic environment. Volatility tests should not be necessary for compounds which can be considered non-volatile from soil and water as predicted from soil/air and water/air distribution coefficients which can be calculated by using water solubility, vapour pressure and soil adsorption (ref. 1-3). Information on the volatility of pesticides and degradation products can also be obtained from degradation studies in air flow through systems. Field studies should only be required where indicated by prediction or by practical observation in laboratory studies.

Test Requirements

Actual volatility in a field situation will depend upon a variety of factors (e.g. soil characteristics, meteorological data), therefore careful recording and reporting of the experimental conditions will be necessary. Field studies should be conducted with the formulated product at the recommended dosage.

Appropriate Test Procedures

Procedures for measuring volatilization have been published for laboratory studies (ref. 1-3) and field studies (4-7).

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5.1.2 Adsorption/Desorption

Adsorption and desorption characteristics of a pesticide in soil contribute to the prediction of the environmental distribution of a chemical. Leaching in soil (5.1.3) and volatilization (5.1.1) from wet soil surfaces are directly influenced by the adsorption/desorption equilibrium in the soil/water system as this can define the extent to which a chemical is available for degradation.

Criteria and test sequence

The adsorption/desorption characteristics should be measured for each pesticide likely to reach the soil or aquatic environment.

The hydrolytic stability should be known before carrying out soil adsorption tests. If hydrolysis occurs it is necessary to analyse for the major hydrolysis products. To be able to define the range of pesticide concentrations to be tested the water solubility of the substance should be known.

Test Requirements

The test should be conducted using the active ingredient, preferably radiolabelled.

For the determination of the adsorption isotherm for a given pesticide in a given soil, the study should be carried out with at least four pesticide concentrations.

Studies in at least two soil types are recommended. The characteristics of the soils used (soil pH, organic carbon, cation exchange capacity and particle size distribution) should be reported.

Appropriate Test Procedures

The most widely-used method for carrying out soil-pesticide adsorption/desorption studies is the slurry procedure where air dry or oven dry soil is shaken with aqueous pesticide solutions of known pesticide concentrations until an equilibrium is reached. The aqueous suspensions are then separated by centrifugation or filtration and the equilibrium concentrations in the water and if necessary in the soil are determined either by direct analysis or after extraction with an organic solvent.

Other methods used for soil adsorption include continuous flow equilibrium (ref. 1) and dialysis (ref. 2) techniques. Although other mathematical models are known, the Freundlich equation is most frequently used to describe adsorption processes in soil. Test methods for determining adsorption/desorption have been recommended (ref. 6, 7).

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5.1.3 Leaching

Data on the leaching behaviour of pesticides are required for all compounds intended for agricultural use, although the need for additional studies may be reduced when measurement of adsorption/desorption coefficients on various soils are available (ref. 1-3). It has been shown that there is a correlation between adsorption and leaching and thus the adsorption constants can be used to estimate the mobility of pesticides.

Criteria and Test Sequence

Soil plate or soil column chromatography can be used to measure leaching of the parent compound. The column model is most appropriate to show the leaching properties of the degradation products of a pesticide after applying the parent compound. Substances which are mobile and persistent may require additional testing under field conditions.

Test Requirements

When plate or column leaching studies with the parent compound are necessary either the active ingredient or formulated material may be used. In field tests the formulations should be used.

The pesticide concentrations tested in the laboratory should have a realistic relatiionship to recommended doses and field leaching studies should be carried out at the recommended rate for the pesticide.

Soil from the same sample as used for the degradation study should be used to study the leaching of pesticide degradation compounds in a soil column model. The need for such a study will depend on the amounts and on the stability of the degradation compounds. Characteristics of the soil used in laboratory studies (pH, organic carbon, cation exchange capacity, particle size distribution, water holding capacity) should be recorded.

Test locations for field leaching studies should be selected according to the recommended use of the pesticide. Meteorological measurements, such as temperatures and rainfall, should be recorded as well as soil characteristics.

Appropriate Test Procedures

Several published methods covering a range from simple laboratory tests to field studies simulate the leaching behaviour of pesticide chemicals in soil.

Soil Layer Chromatography

Soil thin and thick layer chromatography are simple and valuable techniques to test the mobility of a pesticide in a soil (ref. 4, 5, 6). The soil to be tested is used as adsorbent and distilled water (on aqueous 0.01 M $CaCl_2$ or $Ca(NO_3)_2$ solutions) as the mobile phase.

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Soil Columns

A review of appropriate soil column studies is given in reference 7.

Lysimeters

Lysimeters can be useful models to study the fate of pesticides in soil/plant systems under outdoor conditions. Standardized model lysimeters are described in ref. 8. Large lysimeter facilities as used to study fertilizer leaching can also be used to investigate the leaching behaviour of pesticides (ref. 9, 10).

Field Leaching

The key problem in the investigation of field leaching is the appropriate method of sampling in order to avoid contamination of the lower soil layers by soil particles from the upper layers. Sampling is best accomplished with special drilling devices to obtain undisturbed soil cores (ref. 11, 12). Sampling of soil water by suction probes is a further technicque used to study the leaching of a chemical under field conditions (ref. 13).

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5.2 Fate in the Environment

5.2.1 Degradation in Soil

Studies on the degradation of pesticides in soil will determine the rate and products of transformation in soil that may be caused by microbiological, chemical and photochemical processes. Despite the fact that microbial degradation is the most important cause of pesticide breakdown, a considerable amount of work has been done to distinguish between these three causes of pesticide degradation in soil. However, information as to whether a pesticide is degraded in particular by microbial, chemical or photochemical mechanisms can be considered of limited relevance from the point of view of environmental safety.

Available information indicates that photochemical degradation is not an important mechanism in the breakdown of pesticides in soil. Furthermore, experiments under laboratory conditions have shown that products identical with hose resulting from microbial and chemical reactions are often formed.

A summary and critical evaluation of experimental models of degradation can be found in a series of pertinent reviews (refs. 1-4). Additional information can be obtained from references 5.8.

Criteria and Test Sequence

Degradation studies in soil should be required only for pesticides likely to reach the soil when used according to recommendations.

Soil degradation tests should be carried out in the laboratory. If the compound is shown to be persistent in these and laboratory soil photolysis studies, field tests should be carried out.

Test Requirements

Pure pesticides or technical material may be used. However, for studies on the products of degradation the use of radiolabelled material is recommended. For field studies, the formulated material is preferred.

The amount of pesticide tested either in laboratory of under field conditions should be in line with use recommendations. The soil used should be freshly sampled agricultural soil e.g. sandy loam, preferably prepared according to procedures described in refs. 9 and 10. Soil characteristics including pH, organic carbon, cation exchange capacity, particle size distribution and water holding capacity should be recorded. An estimation of microbial activity at initiation of the study is desirable. The use of stored standard soil (ref. 8) should be avoided. Rate studies should be carried out in a minimum of two soils, whereas sufficient information on pathways can be obtained from experiments in one soil only (ref. 3).

The incubation temperature and the soil moisture should be specified. Studies should normally be carried out under aerobic conditions. However, when the pesticide is recommended for use in flooded soils (e.g. paddy rice culture) laboratory studies should simulate these conditions.

Field Tests

Field test guidelines should follow the recommendations for field residue trials (ref. 11) and acceptable procedures can be found in refs. 2 to 6.

Soil Photolysis Tests

Laboratory systems presently available have been recently reviewed (ref. 3 and 4).

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5.2.2 Degradation in the Aquatic Environment

Studies on the degradation of pesicides in water give information on the rate and products of transformations by hydrolysis, photolysis and biodegradation. When studying aquatic systems it should be recognized that the bottom and suspended sediments of ponds, rivers, streams, etc. in general play an important role in determining the fate of pesticides. Since it is impossible to maintain the environmental quality of natural waters under laboratory conditions, the considerations of water/sediment systems may be more useful.

Numerous laboratory methods for determining the fate of chemicals in aquatic environments are quoted in the literature (ref. 1). However, for the incubation of natural water/sediment systems under laboratory conditions few generally accepted test procedures are available. Investigations of the fate of pesticides in such systems together with studies of hydrolysis and photolysis will, however, be of value in understanding of their behaviour in aquatic environments.

A short, simple evaluation of hydrolytic potential of the compound is all that is generally necessary as a first stage. The available data (refs. 2-4) indicate that H^+ and OH^- contribute significantly to catalysed hydrolysis in natural freshwaters. Hence laboratory studies in buffered water at a range of pH are likely to yield those compounds which are also formed in natural environments. Laboratory studies of the degradation of pesticides in water/sediment systems do not normally take account of natural photodegradation which is complicated by the presence of light absorbers or photosensitizers (e.g. humic and fulvic acids, and riboflavin).

Criteria and Test Sequence

Studies are required for all pesticides applied directly to water bodies or those for which their use pattern is likely to result in water contamination. Tests on biodegradation, hydrolysis and photolysis should generally be carried out under laboratory conditions to determine rates and products of degradation. If laboratory tests indicate that compounds may persist in the aquatic environment at concentrations which could put aquatic organisms at risk, field testing should be considered.

Test Requirements

1. Biodegradation studies:

The sediment used should be analysed for its pH, organic carbon, cation exchange capacity and particle size distribution. The water pH should also be measured.

Pure or technical material may be used and the use of radio-labelled pesticide is recommended for studies on the products of degradation. Formulated material is preferred for field studies. A pesticide should be tested at levels approximating those likely to occur in bodies of water when used as recommended.

Test duration should not exceed three months.

In laboratory studies the incubation temperature should be kept constant.

2. Hydrolysis:

The analytically pure active ingredient in sterile buffered water should be used and the use of radio-labelled compounds is valuable whenever possible.

A single concentration should be tested and this should be preferably within the range of water solubility. Where lack of solubility is a limiting factor the addition of organic solvents (e.g. acetonitrile) at low concentration may be necessary.

Sealed, sterile containers are required to maintain sterility and minimize volatilization. The test should be carried out in darkness at pH values within the ranges: acidic, pH 3-5.5, neutral, pH 5.5-8, basic, pH 8-10 and each value separated by at least 2 pH units. Solutions should be maintained at not less than 70°C for 48 hours.

3. Aqueous photolysis:

Analytically pure active ingredient in sterile distilled water should be used. The use of a commercial formulation should be avoided as the constitutents may cause indirect photochemical reactions. For ease of analysis radio-labelled chemical should be used wherever possible.

A single concentration should be tested and this should be preferably within the range of water solubility and at a level approximately that is likely to occur in aquatic environments. Whilst this is necessary to minimize reactions which would not occur at likely environmntal concentration, higher rates may be required to facilitate identification of photoproducts. Where solubility is a limiting factor a suitable non-photosensitizing cosolvent (e.g. acetonitrile; ref. 4) may be used.

The test should be carried out within the pH range 5-8 (preferably near neutrality) in air-saturated distilled water. Studies at more than one pH value may be necessary for compounds that ionize or protonate.

Sealed, sterilized glass containers (capable of transmitting 290 nm and above) are required such that biodegradation is eliminated and volatilization minimized.

Artificial light sources are recommended and should resemble sunlight in wavelength distribution, especially in the U.V. region. Filters should be included to eliminate wavelengths below 290 nm. The manufacturer's specification for the lamp(s) and filters must be quoted. However, consideration should be given to the effect of ageing on the relative intensity of different wavelengths. Chemical actinometers could also be valuable in such studies. Samples should be exposed to the artificial light source for a sufficient period of time to allow for the estimation of the half-life. Controls should be kept in the dark, all conditions being comparable, to quantify the chemical contribution to any transformation processes.

Although the rates of photochemical reactions are not appreciably influenced by temperature the test should preferably be carried out at constant temperature.

Appropriate Test Procedures

1. Biodegradation studies:

In the absence of established test procedures the following laboratory method is suggested (ref. 5 and 6). Water/sediment systems representative of likely environmental application or contamination sites (e.g. ditches, rivers, etc.) should be used. The water and sediment should be collected from such environments either separately, to be mixed in the laboratory, or as water/sediment cores. Where anoxic conditions are required in the sediment, the water/sediment system should be preincubated prior to application of the pesticide and it may also be necessary to measure Redox potential (Eh). Wherever possible, the enclosed incubation system with an air flow-through should be used such that degradation products evolved into the air-stream may be collected. No specific procedures can be advised for field studies at this time.

2. Hydrolysis:

If less than 10% degradation is observed in the biodegradation studies the chemical can be considered hydrolytically stable and will require no further testing. If more than 10% degradation is observed a further study should be carried out at a lower temperature. If the results then indicate the need for further work, a number of test procedures of varying degrees of complexity are available (refs. 7-12).

3. Aqueous photolysis:

A number of procedures can be found in references 8 and 9, many of which are of greater complexity than are generally required. The procedure outlined above in the test requirements should be adequate in most circumstances.°

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6. EFFECTS IN THE ENVIRONMENT

6.1 Soil Non-Target Micro-Organisms

The relationship between changes in soil micro-organisms and soil fertility is ill-defined. Soil biota are very resilient and major changes in micro-organism populations occur under natural conditions and are often without effect on fertility. Thus, major changes in one section of the flora can be compensated for by another section of the flora so that overall functions are not disturbed. In studying the effect of pesticides on soil micro-organisms, work should therefore be directed to studying effects on soil functions rather than on specific organisms.

Information on changes in these functions caused by pesticides can sometimes be useful in predicting possible effects on soil fertility but even the information on overall functions must be interpreted with great caution.

Criteria and Test Sequence

When data concerning selected physical and chemical properties, use pattern and degradation indicate the probability of high environmental concentrations, relevant studies should be selected from the following test sequence.

Studies of effects on micro-organisms usually start with an estimate of the effect of a pesticide on their overall function as indicated by their respiration rate under laboratory conditions. If this is significantly changed, its importance under field conditions should be further studied. A similar sequence is suggested for studies concerning the transformation of nitrogen in soil. Where applicable, studies on nitrogen fixation by nodulated plants could form part of the test sequence but this aspect can only be studied in the glasshouse or small scale field tests.

Test Requirements

Technical or formulated material may be used. Dosages tested must have a realistic relationship to the recommendations for use.

The soil used in the test should be freshly sampled agricultural soil e.g. sandy loam, preferably prepared according to procedures described in reference 1 and 3. Soil characteristics including pH, organic carbon, cation exchange capacity, particle size distribution and water holding capacity should be recorded.

Appropriate Test Procedures

There is general agreement that a "functional" approach of studying pesticide effects on soil microflora is preferable to a "population" approach and this should be borne in mind when considering appropriate procedures. Following several Symposia and International Workshops held during the period 1973-79, "Recommended Tests for Assessing the Side-Effects of Pesticides on the Soil Microflora" were published together with a proposal for the interpretation of results (ref. 1). Reference 2 also proposes test procedures following the "functional" approach and covering soil respiration tests, organic matter turnover, nitrogen transformation and fixation. Reviews of suitable methods are given in references 3 and 4.

Guidance is available on the "leaf--litter-bag" test by which the breakdown of organic matter can be studied under field conditions (6).

The interpretation of results should take account of changes known to be induced in soil microbiological functions by natural stress but agreement is needed to define the degree of change regarded as significant. The latter should be judged on the basis of soil fertility. The model suggested in ref. 1 provides an appropriate and constructive framework for interpreting results.

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6.2 Soil Non-Target Macro-Organisms

The effect of changes in the population of soil macro-organisms on soil fertility is largely unknown. Consequently, apart from considering earthworms, there is little value in developing data for individual species and it is preferable that studies should be confined to effects on soil functions. The two main functions are turnover of organic matter and predation but this latter point is dealt with under beneficial arthropods (see 6.4).

Useful procedures have been described to study turnover of organic matter (ref. 1) based on studying the fate of leaf discs buried in the soil in small network containers. The method embodies the effects of micro-organisms as well as macro-organisms and gives a good indication of any serious impairment of the soil's ability to break down organic matter.

Earthworms are important to organic matter degradation and are considered by many authorities to be of particular importance both from an agricultural and environmental point of view. Since agriculturally important species cannot as yet be bred easily, laboratory experiments with these species can only be conducted on field collected worms. This makes laboratory testing relatively cumbersome. In contrast, Eisenia foetida, although not a common species in agricultural soils, can easily be bred in the laboratory and therefore has been suggested as a test organism. Standard protocols for testing earthworm toxicity in the laboratory using this species have been developed by OECD. (Ref. 9)

As earthworms form a significant food source particularly for certain birds, residues of compounds in earthworms can be of interest for those compounds with a significant toxicity to birds and a tendency to bioaccumulate. The biology of earthworms is fully described in reference 2. Field populations are often sampled by the method given in reference 3 but sampling procedures are still under development (6 and 7). An example of an integrated study on toxicity of a pesticide to earthworms is reported in reference 4.

Criteria and Test Sequence

The statement on selection of compounds made in 8.1 is equally applicable to soil invertebrate macro-organisms. However, in view of the significance attached to earthworms, assessment of toxicity to earthworms is usually required regardless of the fate of the compound in the environment. Data on residues in earthworms should be required only for compounds with a significant toxicity to birds and with potential for bioaccumulation.

For earthworms, the test sequence may include simple laboratory toxicity tests as well as field tests to assess hazard to earthworm populations. For organic matter breakdown only a direct field test is suggested because appropriate conditions cannot be simulated in the laboratory.

Test Requirements

There should be no significant mortality in controls in laboratory tests. In field tests, untreated control plots should be included.

Technical or formulated material may be used. Field tests should reflect the recommended dosage and treatment regime of the compound and studies should be conducted in such a way as to give a reliable estimate of the effect which is likely to arise when the product is used under field conditions. Data from tests on recommended formulations which limit the availability of the active ingredient in soil should be given greatest weight.

When required, residue data for earthworms should be obtained on worms without their gut contents.

Appropriate Test Procedures

1. Earthworms - laboratory tests

Earthworms, eiher laboratory reared or collected from the field, can be exposed to treated soil in the laboratory as described in ref. 5. Another test procedure has been validated by a ring test using 12 pesticides (ref. 10).

2. Earthworms - field tests

Populations should be assessed on treated and untreated plots as described in ref. 4. For sampling earthworms in the field, the method in ref. 3 is widely used. Field tests with earthworms including residues analysis are proposed in reference 8.

3. Leaf litter breakdown

A simple procedure for following the breakdown of buried leaf discs using the methods described in ref. 1 is included in ref. 8.

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6.3 Honey Bees

Honey bees are important both as pollinating insects and as producers of honey and they are an important resource that should be preserved.

Bees are at risk from pesticide applications to crops in flower and crops containing weeds in flower or to crops infested with aphids which secrete honey dew. Contamination may occur principally by direct contact with the spray droplets, by contact with residual deposits on foliage or through drinking contaminated water.

Methods of assessing the potential hazard to bees from laboratory tests and the actual hazard in the field situation have been under investigation in several centre for many years. The report of a symposium on "The harmonisation of methods for testing the toxicity of pesticides for bees" arranged by the International Commission for Bee Botany in September, 1980, should be consulted (Ref. 7).

Certain regulatory authorities have already incorporated requirements for honey bee test data, e.g. France, Federal Republic of Germany and United Kingdom.

Criteria and Test Sequence

Data should be required only for compounds with a use pattern likely to put bees at risk.

The test sequence should take account of the pesticides type and its use pattern and include laboratory tests to assess the oral and contact toxicity of the compound with provision for further tests to be used in cases where the real hazard cannot be assessed on the basis of the laoratory data alone.

Compounds giving contact LD50 figures greater than 10 ug ai per bee in the topical tests, or failing to kill bees (less than 10% mortality) at twice their recommended field application rate in the direct spraying tests, can be considered safe to bees in recommended use. Compounds not meeting these criteria, and which are intended for use where bees might be at risk, should be subject to field experimentation.

Test Requirements

There should be no significnt mortality in controls in laboratory tests.

Technical or formulated material may be used. Apprpriate reference compounds should be included in acute toxicity tests.

Rates used for laboratory studies other than acute toxicity tests should be within the range of possible exposure resulting from field use of the compound. Field tests should reflect the use recommendations of the compound if these recommendations are likely to put bees at risk. Data from tests on recommended formulations which limit the availability of an active ingredient to bees should be given greatest weight.

Suitable Test Procedures

Laboratory tests

1. Oral toxicity

Compound dispersed in sugar or honey water should be presented to individual or small groups of worker bees at a range of dosages such that an LD50 can be calculated. The test procedures in references 1, 4, 5 and 6 are appropriate. Certain solid formulations may be difficult to test by these methods and technical material dispersed in acetone may be used although the presence of extraneous solvent in test solutions is undesirable.

2. Contact toxicity

The compound dispersed in acetone should be topically applied to individual worker bees in a range of dosages such that an LD50 can be calculated. Suitable test procedures are described in references 1, 3, 5 and 6. Although the use of carbon dioxide anesthesia is not recommended, it may be used provided that no significant mortality occurs in the controls.

Field Experiments

1. Small scale tests

Depending on the specific properties of the test product, acceptable data can be obtained from small field cage tests. Useful procedures can be found in references 5 and 6.

2. Large scale tests

If the status of a compound relative to bees cannot be satisfactorily resolved by the preceeding tests, then a large scale field test should be undertaken. This will most probably be the case for insecticides for which it is intended to make the specific claim that they are non-toxic to bees. Such tests are discussed in ref. 7. Useful procedures are given in references 2, 5 and 6.

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6.4 Beneficial Arthropods

Parasites and predators can be important and beneficial in regulating pest populations. Pest resurgence and secondary pest appearance may follow disturbance of these ecological relationships and the influence of pesticides on beneficial arthropods is of particular importance in integrated pest control systems. The diversity of species involved as well as regional differences have greatly affected possibilities for the development of widely applicable test procedures. Much further work is in progress but at this stage only preliminary results can be indicated.

Criteria and Test Sequence

Data should be required only for compounds with a use pattern likely to influence parasites and predators and for which general wide-spectrum laboratory screening tests reveal that there is significant insecticidal activity. These studies are especially important where specific claims are made for selectivity or where the chemical is recommended for use in integrated pest control systems.

The test sequence may include laboratory tests to assess contact toxicity but observational information from field performance trials where the

pest/predator or parasite complex is understood should carry greater weight. Where a claim is made for selectivity or for use in integrated pest control systems,. observations from actual use programmes would be expected. Observations on the effect of the pesticide on those predators that inhabit the soil surface, notably carabid and staphylinid beetles may also be important.

Test Requirements

In general, the test organisms will be determined by the local pest/predator or parasite complex to which the pesticide is to be applied.

Mortality in controls should not be significantly higher than the natural population.

Technical pesticides or formulated material may be used in the tests which should be designed to generate data from which a conclusion can be drawn regarding the comparative toxicity to the parasite/predator and host/prey.

Field tests should reflect the recommended use pattern of the compound.

Appropriate Test Guidelines

Information on certain important predators and parasites and about test methods can be found in ref. 1 and attenion is drawn to the proceedings of the symposium "Pesticides and Beneficial Arthropods" held during the XVth International Congress of Entomology at Washington in 1976, (ref. 2). Accepted practices of field evaluation trials and arthropod population sampling should be followed for data obtained under use conditions. A procedure for studying soil surface dwelling predatory beetles has been proposed (ref. 3).

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6.5 Non-Target Aquatic Organisms

If a pesticide or its breakdown are likely to contaminate surface waters, their toxicity to aquatic organisms should be tested. There are some differences in susceptibility beween fish species normally used in test systems but determination of acute toxicity using one fish species only should be sufficient to identify compounds potentially dangerous to fish (ref. 1-6). Damage to aquatic invertebrates and phytoplankton may be of ecological relevance and may have an indirect effect on fish. Thus testing toxicity to appropriate species is desirable.

Criteria and Test Sequence

Tests on the toxicity of pesticides to aquatic organisms should be required for compounds intended for outdoor use if they or their breakdown products are likely to contaminate water. The test sequence should take account of the use pattern and should commence with laboratory tests for acute toxicity. Longer-term toxicity studies are usually required for pesticides applied directly to water bodies. They may also be needed if degradation studies indicate that the compound is likely to reach water and persist in it at concentrations greater than one hundredth of the acute toxicity. Bioaccumulation studies on fish will normally be required if a pesticide is likely to reach water, persist for an appreciable time and if the octanol/water partition coefficient is greater than 1000 or if the substance is known from biokinetic studies to accumulate in animal tissues.

If the results of laboratory studies do not allow adequate hazard assessment then field studies may be required. These studies should enable observations to be made of the recovery of affected populations and of indirect effects on the various species in the system.

Test Requirements

There should be no significant mortality in controls in laboratory tests.

Technical pesticides or formulated material may be used but solvents that do not occur in formulations should not be used to prepare test dispersions of technical material (ref. 1). Data from tests on recommended formulations that limit the availability of the active ingredient to aquatic organisms should be given greatest weight.

For the preparation of test solutions the water used should be of known quality, (e.g. standardized tapwater (ref. 1) or reconstituted water (ref. 2, 3 and 6) preferably of medium hardness.

Methods for fish toxicity and bioaccumulation studies are based on static, semi-static or continuous flow procedures. The method should be chosen according to circumstances. The concentration of the compound in the water should be determined at regular intervals to check the level of exposure.

1. Acute toxicity to fish:

Several comparable procedures are well established and widely accepted (refs. 1, 4, 5, 6). The LC50 should be calculated for the total exposure time. Intermediate mortality figures should also be provided.

2. Prolonged exposure to fish:

A test procedure for subacute toxicity testing is described in ref. 15. Egg-larvae and life cycle studies are still under development and are not yet widely recognized. Examples of these procedures are available (ref. 2).

3. Accumulation studies with fish:

Procedures are given in ref. 2, 7 and 8. Concentrations should be low enough to prevent significant mortality.

4. Toxicity to lower aquatic organisms:

For fish food organisms, the water flea Daphnia magna is widely available as a test species. Methods for acute toxicity tests are given in ref. 9-11. Ref. 10 includes a Daphnia reproduction test. In certain cases it may be desirable to evaluate toxicity to algae as primary producers at the lower end of the aquatic food chain (ref. 12, 13 and 14).

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6.6 Birds

Birds are considered worthy of protection in many countries although attitudes to their preservation vary greatly throughout the world. The role of birds in insect control is of definite importance, though difficult to quantify. Many bird species are common in agricultural and surrounding areas and may therefore be exposed to pesticide formulations and/or pesticide residues.

Methods of assessing the potential hazard of pesticides to birds from laboratory and pen tests are under investigation and certain regulatory authorities have already incorporated or are currently considering requirements for bird test data, notably the United States and the United Kingdom. Acute oral LD50 and 5-day exposure dietary LC50 are suitable for predicting potential short term adverse effects to birds (ref. 1, 4, 5, 6 and 7). Although there may be differences in susceptibility between bird species (ref. 7), current knowledge indicates that with rare exceptions the values will fall within an order of magnitude. The use of one bird species should normally be sufficient to recognize compounds potentially dangerous to birds. Testing additional species should only be required if a pesticide is applied in such a way as to give rise to the possibility of a significant exposure to birds e.g. in the case of seed treatment pesticides, granulated products or baits or if there are indications for considerable interspecies variation.

Criteria and Test Sequence

Data should only be required for pesticides with a use pattern likely to put birds at risk and the test sequence should take account of the type of pesticide and its use.

The test sequence should include a laboratory test to assess the acute oral toxicity (LD50) on one bird species. However, if range finding studies indicate a potential LD50 greater than 500 mg/kg an LD50 study should not be required. If considerable exposure of birds is likely to occur and if there is indication of cumulative action from toxicity studies with mammals, the 5 days exposure LC50 should be determined for one bird species. In certain cases especially when long term exposure is likely to occur other studies such as reproduction studies in suitable species may be required. Additional testing e.g. pen tests, should be provided in cases where the real hazard cannot be judged on the basis of laboratory data alone.

Pen tests should be required only if the oral toxicity of a pesticide, when taken in conjunction with the exposure pattern or residue levels in the food of important bird species indicate need. Pen tests should be undertaken with the formulated product at the recommended dosage and a multiple of that rate. Application should exactly follow the directions for use.

If pen tests do not allow a reliable hazard assessment, field observations under practical conditions using the formulated product at the recommended application rate may have to be carried out. The data obtained under these practical conditions should be given greatest weight.

Where cumulative effects are indicated, accumulations studies may need to be undertaken. Observation should include effects on food intake, breeding behaviour, egg laying, egg hatchability, survival of young, etc. If accumulation occurs it is desirable to estimate pesticide residues in suitable organs from the birds used in these toxicity studies, so that the toxicological significance of residues found in practice can be assessed.

Test Requirements

There should be no significant mortality in controls in laboratory tests.

Technical pesticides or formulated material may be used.

Suitable bird species include pigeons, quails, pheasant, ducks and Bengalese finch. All birds should be pen-reared. No wild-caught birds should be used since previous history, age, etc., are known. The domestic hen is not considered a suitable species. Restriction to indigenous bird species would impede international harmonisation efforts.

Appropriate Test Procedures

1. Laboratory tests

1.1 Avian single dose oral LD50.

The compound is dispersed in water or another inert carrier liquid and applied to the birds by intubation (ref. 1, 4, 6). Another suitable method of administration is accomplished by inserting a gelatin capsule containing the chemical to the level of the bird's crop or proventriculus (Ref. 1, 4, 7).

Geometrically spaced dosage levels should enable an LD50 to be calculated with confidence limits. However, an estimation of the approximate LD50 will be sufficient in some cases.

1.2 Avian dietary LC50

The compound is dispersed where feasible without the use of a diluent in a standard commercial bird diet (mash form) and given to the test birds as the only feed for a five day period, followed by at least 3 days of untreated diet.

Geometrically spaced dosage levels should enable an LC50 to be calculated with confidence limits (ref. 5). However, an estimation of the approximate LC50 will be sufficient in some cases.

2. Pen Tests

Depending on the specific properties of the tested product, acceptable data could be obtained from short-term/small pen and long-term/large pen tests (ref. 2). Procedures are still under development.

3. Large Scale (field) Tests

If the effect of a pesticide compound on birds cannot satisfactorily be elucidated by the preceding tests, a large scale (field) test should be undertaken to resolve the problem. A useful protocol is given in reference 3.

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